

RECEIVED
CENTRAL FAX CENTER

NOV 14 2005

Application No.: 10/711,886
Filing Date: October 12, 2004
Group Art Unit: 3743
Examiner: D.J.D. Greene
Attorney Docket No.: 22727-117**REMARKS**

The pending Office Action addresses claims 1-29, all of which stand rejected. Reconsideration is respectfully requested in view of the remarks submitted herewith.

Rejections Pursuant to 35 U.S.C. §102

The Examiner rejects claims 1, 2, 5, 6, 7, 8, 10, 11, 13, 14, 17, 18, 19, and 24-29 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,371,112 of Bibi. Applicant respectfully disagrees.

Claims 1, 2, 5, 6, 7, 8, 10, 11, 13, and 14

Independent claims 1 and 10 are directed to a system for maintaining an open airway and include a mouthpiece that is adapted to form a substantially sealed cavity within a patient's mouth. The mouthpiece is further adapted to be coupled to a *negative pressure generator* that is effective to create a negative pressure within the substantially sealed cavity to prevent the soft tissues of the upper airway from collapsing. Bibi does not teach or even suggest a mouthpiece that is adapted to couple to a negative pressure generator. Rather, Bibi teaches a *self-contained CPAP device* that is designed and constructed to maintain sufficient pressure in a patient's upper airway such that collapse thereof is prevented. In particular, the device includes a mouthpiece that is coupled to a *tube* which connects the mouthpiece to a mask that is placed on a user's nose. The device is self-contained because it allows air to flow from the patient's mouth and through their nose, thereby creating a positive pressure through the nose to maintain an open airway. Accordingly, since the mouthpiece is coupled to the mask, it cannot be coupled to a negative pressure generator, as required by independent claims 1 and 10. To the contrary, because the device is self-contained, it "functions independently of, for example, a pump, a compressor, a pressurized gas cylinder and an electro-hydrolytic oxygen source." Column 7, lines 21-23. Claims 1 and 10, as well as claims 2, 5, 6, 7, 8, 11, 13, and 14 which depend therefrom, therefore distinguish over Bibi and represent allowable subject matter.

Application No.: 10/711,886
Filing Date: October 12, 2004
Group Art Unit: 3743
Examiner: D.J.D. Greene
Attorney Docket No.: 22727-117

Claims 17-19 and 24-29

Independent claim 17 recites a method for maintaining an open airway by forming a substantially sealed cavity within a patient's mouth and creating a *negative pressure* therein to prevent the soft tissues of the upper airway from collapsing. As indicated above, Bibi does not teach or even suggest a method whereby a negative pressure is created in a substantially sealed cavity to prevent the soft tissues of the upper airway from collapsing. To the contrary, Bibi teaches a device that is adapted to create a *positive pressure* to maintain an open airway. In particular, the device of Bibi includes a mask that is placed on a user's nose and a tube having bidirectional valves extending therefrom and into a mouthpiece placed in the user's mouth. In use and upon exhalation by the user, an inflatable body located within the tube inflates and the valves within the tube open. This establishes a flow of air under a slight positive pressure through the user's nose and into the interior of the mouth and subglottal region of the airway. During subsequent inhalations, air continues to flow through the valves to maintain a *positive pressure* in the subglottal region of the upper airway, causing the airway to remain open. Accordingly, independent claim 17, as well as claims 18, 19, and 24-29 which depend therefrom, distinguish over Bibi and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. §103

The Examiner rejects dependent claims 3, 12, and 20 pursuant to 35 U.S.C. §103(a) as being obvious over Bibi in view of U.S. Patent No. 6,494,209 of Kulick. Claims 4 and 21-23 are also rejected pursuant to 35 U.S.C. §103(a) as being obvious over Bibi in view of U.S. Patent No. 6,405,729 of Thornton, and claims 9 and 16 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Bibi in view of U.S. Publication No. 2005/0103347 of Curti. As discussed above, Bibi does not teach or even suggest a system or method that creates a negative pressure in a substantially sealed cavity to prevent the soft tissues of the upper airway from collapsing. Kulick, Thornton, and Curti do not remedy the deficiencies of Bibi. Accordingly, claims 3, 4, 9, 12, 16, and 20-23 distinguish over Bibi in view of Kulick, Thornton, and Curti and represent allowable subject matter.

RECEIVED
CENTRAL FAX CENTER

NOV 14 2005

Application No.: 10/711,886
Filing Date: October 12, 2004
Group Art Unit: 3743
Examiner: D.J.D. Greene
Attorney Docket No.: 22727-117

Conclusion

Applicant submits that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite the prosecution of this application.

Respectfully submitted,

Date: November 14, 2005



Lisa Michaud, Reg. No. 44,238
Attorney for Applicant(s)

Nutter, McClennen & Fish, LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
Tel: (617)439-2550
Fax: (617)310-9550

1475676.1